Attorney Docket No. A-67032-2 Attorney File No.: 463037-00022

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of

BAMDAD et al.

Serial No. 10/016,416

Filed: December 10, 2001

For: Detection of Target Analytes Using

Particles and Electrodes

Examiner: LU, Frank Wei-Min

Art Unit: 1634 Confirmation No.: 1226

CERTIFICATE OF ELECTRONIC TRANSMISSION

Thereby certify that this correspondence, including listed enclosures, is being electronically transmitted in Portable Document Form (PDF) through EFS-Web via Hyper Text Transfer Protocol to the United States Patent and Trademark Office's Patent Electronic Business Center on:

Office's Paterit Electronic Business Oction on

Dated: October 27, 2006

Signed: Rept Youehara

AMENDMENT AND RESPONSE TO NON-FINAL OFFICE ACTION

Mail Stop Amendment Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

Applicants have considered the Office Action mailed June 29, 2006 and offer the following amendments and remarks. This response is being filed on or before October 29, 2006, with request for one-month extension of time, thus making it a timely response. Although the Applicants do not believe any additional fees are required, the Commissioner is authorized to charge any additional fees that may be required, or credit any overpayment to Deposit Account No. 50-2319 (File No. 463037-00022; Docket No.: A-67032-2). Please amend the application as follows:

Amendments to the Claims begin on page 2 of this paper.

Remarks begin on page 3 of this paper.

AMENDMENTS TO THE CLAIMS

This listing of claims will replace all prior versions and listings of all claims in the application.

Listing of Claims

- 1-17. (canceled)
- 18. (currently amended) A composition comprising:
- a) a substrate comprising an array of working electrodes, wherein each electrode comprises a first binding ligand;
 - b) a plurality of colloids, each comprising:
 - i) a second binding ligand; and
 - ii) an electron transfer moiety: and
- c) a detector capable of detecting a voltage associated with electron transfer from said electron transfer moiety.
- 19. (canceled)
- 20. (previously presented) The composition of claim 18 wherein said plurality of colloids further comprise a self-assembled monolayer.
- (previously presented) The composition of claim 20 wherein said self-assembling monolayer comprises an alkyl chain.
- 22. (previously presented) The composition of claim 18 wherein said substrate is a printed circuit board.
- 23. (previously presented) The composition according to claim 18 wherein said electrodes are gold.
- 24. (previously presented) The composition according to claim 18 wherein said electron transfer moiety is a transition metal complex.
- 25 (previously presented) The composition according to claim 24 wherein said transition metal complex is ferrocene.
- 26: (withdrawn) The composition according to claim 18 wherein said ETM is an organic ETM.
- 27. (previously presented) The composition according to claim 18 wherein said first binding ligand is a first nucleic acid and said second binding ligand is a second nucleic acid.

28-37. (canceled)

REMARKS

Reconsideration of the claims in light of the following remarks is requested. Claims 18 and 20-27 are pending. Claim 18 is amended. Claims 1-17, 19, and 28-37 are canceled. Claim 26 is withdrawn from further consideration.

Applicants have not dedicated or abandoned any unclaimed subject matter and moreover have not acquiesced to any rejections made by the Patent Office. Applicants reserve the right to pursue prosecution of any presently excluded claim embodiments in future continuation and/or divisional applications.

Claim Amendment

Claim 18 is amended for technical clarity.

Claim Rejections Under 35 U.S.C. § 103

Claims 18, 20, 24 and 27 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Sigal et al. (U.S. 6,319,670) ("Sigal") in view of Meade et al. (U.S. 5,770,369) ("Meade") and Roberts et al. (U.S. 5,958,791) ("Roberts").

Claim 21 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over Sigal, in view of Meade, and Roberts, as applied to claims 18, 20, 24 and 27, and further in view of Bamdad et al. U.S. 5,620,850) ("Bamdad").

Claim 22 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over Sigal in view of Meade, and Roberts, as applied to claims 18, 20, 24, and 27, and further in view of Gerpheide et al. (U.S. 5,565,658) ("Gerpheide").

Claim 23 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over Sigal in view of Meade and Roberts as applied to claims 18, 20, 24, and 27, and further in view of Kayyem et al. (U.S. 6.096,273) ("Kayyem").

Claim 25 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over Sigal in view of Meade and Roberts as applied to claims 18, 20, 24, and 27, and further in view of Kayyem.

The Applicants traverse each of the rejections based on the arguments presented in the previous response and herein.

1. Law of Obviousness

When rejecting claims under 35 U.S.C. §103, the Examiner bears the burden of establishing a prima facie case of obviousness. See, e.g., *In re Bell* 26 USPQ2d 1529 (Fed. Cir. 1993); M.P.E.P. S § 2142

To establish a *prima facie* case, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the references or to combine their teachings. M.P.E.P. §2142. However, the claimed combination cannot change the principle of operation of the primary reference or render the reference inoperable for its intended purpose. M.P.E.P. 2145. As explained in more detail in M.P.E.P. § 2143.01 VI:

If the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims prima facie obvious. In re Ratti, 270 F.2d 810, 123 USPQ 349 (CCPA 1959).

Therefore, if the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the Examiner fails to establish a prima facie case because the teachings of the references are not sufficient to render the claims prima facie obvious.

The Examiner Has Failed to Establish A Prima Facie Case of Obviousness Because the Alleged Combinations Change the Principle of Operation of the Primary Reference, Sigal.

Claims 20-27 depend from claim 18, which recites: "a detector capable of detecting a voltage associated with electron transfer from said electron transfer moiety."

The primary reference relied upon by the Exam is Sigal, which as the Examiner concedes, does not disclose "a detector capable of detecting a voltage associated with electron transfer from said electron transfer moiety."

Further, as presented in the previous response, Sigal is directed to compositions and methods used to measure the presence of analyte by measuring electrochemiluminescence triggered by a voltage imposed on a working electrode. See col. 1, lines 15 – 19 and lines 48-49. It discloses that such electrochemiluminescence is measured with a photomutiplier tube (PMT). See col. 17, lines 26-27. It

also discloses compositions and methods for conducting electrochemiluminescence binding assays using microparticles that include electrically conductive material. See Abstract.

The Examiner relies on Meade to provide motivation to modify Sigal to use electronic detection. However, as noted, the principal of operation of Sigal is chemiluminescence-based, which is different from electronic detection as claimed for the invention. Sigal is based on optical detection of light and NOT a change in voltage. Therefore, replacing the optical detector in Sigal with the voltage detector of Meade totally changes the principal of operation of Sigal.

Because the proposed modification of Sigal would completely change the principle of operation of Sigal, the teachings of the references are not sufficient to render the claims prima facie obvious.

Assume, arguendo, the Examiner has established a prima facie case of obviousness, the prima facie case dissolves because Applicants have provided rebuttal evidence -replacing the optical detector in Sigal with the voltage detector of Meade totally changes the principal of operation of Sigal. As the Court stated in In re Kumar

The prima facie case is a procedural tool, and requires that the examiner initially produce evidence sufficient to support a ruling of obviousness; thereafter the burden shifts to the applicant to come forward with evidence or argument in rebuttal. When rebuttal evidence is provided, the prima facie case dissolves, and the decision is made on the entirety of the evidence.

In re Kumar, 76 USPQ2d 1048, 1050 (Fed. Cir. 2005) (citations omitted).

As such, the Examiner has failed to make a prima facie case of obviousness, and even there is a prima facie case, it is rebutted, and the rejections, accordingly, are respectfully submitted to be improper and asked to be withdrawn.

CONCLUSION

Applicants respectfully submit that the claims are now in condition for allowance and early notification to that effect is respectfully requested. If the Examiner feels there are further unresolved issues, the Examiner is respectfully requested to phone the undersigned at (415) 781-1989.

Respectfully submitted, DORSEY & WHITNEY LLP

Robin M. Silva, Reg. No. 38,304

Filed Under 37 C.F.R. § 1.34

Customer No : 32940 555 California Street, Suite 1000 San Francisco, CA 94104-1513 Telephone: (415) 781-1989

Facsimile: (415) 398-3249

Dated: